

REMARKS

I. Introduction

The Office Action mailed April 30, 2008, has been carefully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of Claims

Claims 1-22 are pending. Claims 1, 9 and 14 have been amended. Support for the amendment is found, *inter alia*, in the specification on page 9, lines 13-15.

III. Summary of the Office Action

In the office action, the Examiner rejects

- 1) claims 1-4, 14-18, and 20-22 under 35 U.S.C. § 103(a) as being obvious over Knapp et al. (U.S. Patent No. 6,235,471) in view of Tang et al. (Chromatography A, 887:265-275, 2000);
- 2) claims 5-8 and 19 under 35 U.S.C. § 103(a) as being obvious over Knapp et al. in view of Tang et al., and further in view of Sato et al. (Journal of Materials Science, 25:4880-4885, 1990);
- 3) claims 9-11 and 13 under 35 U.S.C. § 103(a) as being obvious over Christel et al. (Journal of Biomechanical Engineering 121:22-27, 1999) in view of Tang et al.; and
- 4) claim 12 under 35 U.S.C. § 103(a) as being obvious over Christel et al. in view of Tang et al., and further in view of Sato et al.

IV. Arguments

Applicants respectfully traverse the rejections for the following reasons:

A. Knapp et al. in view of Tang et al.

The cited references fail to disclose every element of the claimed invention. In particular, none of the cited references discloses that the nucleic acid binds to the sol-gel matrix as recited by independent claims 1 and 14. Knapp et al. disclose microfluidic devices for biochemical analysis, including PCR and DNA sequencing (column 11, lines 2-3). There is, however, no disclosure of any solid phase extraction (SPE) of nucleic acid. The Examiner correctly notes that Knapp et al. fail to disclose a sol-gel matrix.

The Examiner, thus, relies on Tang et al. to disclose a sol-gel matrix; however, Tang et al. disclose a sol-gel matrix for capillary electrochromatography, not SPE. Because chromatography is a method of separation based on different motilities through a stationary phase (the sol-gel in this case), there is no surprise that Tang et al. fail to disclose binding of the nucleic acid to the sol-gel matrix. Chromatography and SPE are two different methods of separation. Chromatography separates components of a mixture based on the different motilities of the components through a stationary phase. On the other hand, SPE captures a single component of a mixture (nucleic acid in this case) on a stationary phase (sol-gel matrix in this case), while letting the other components through. The captured component is then released from the stationary phase using an extraction solvent. These two methods are completely different. Chromatography separates all the components of a mixture based on their motility differences, while SPE separates only selected component(s) based on that component's affinity to a stationary phase. As such, because the Knapp et al. and Tang et al. do not contemplate or

disclose SPE, they naturally do not disclose that the nucleic acid binds to the sol-gel matrix.

The Examiner also relies on Sato et al. to disclose “control of pore size distribution through so-gel process ... and ... pores [*sic*] sizes of ca. 1 micron obtained with certain additives” (Office Action, page 4). However, because Sato et al. fail to cure the deficiencies of Knapp et al. and Tang et al., their combination still cannot render the present invention obvious.

Therefore, as noted above, by failing to disclose every element of the claimed invention, the cited references cannot render the present invention obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejection.

B. Christel et al. in view of Tang et al.

The cited references fail to disclose every element of the claimed invention. In particular, none of the cited references disclose a step of “loading the sample onto the microcolumn under conditions conducive for nucleic acid binding to the sol-gel matrix” as recited by independent claim 9. Christel et al. discloses DNA capture on silicon dioxide surfaces of a fluidic microchip (see Abstract). The DNA is then eluted from the silicon surface by an aqueous ethanol solution (see Abstract). There is no disclosure of binding of nucleic acid to a sol-gel matrix.

The Examiner relies on Tang et al. to disclose a sol-gel matrix; however, Tang et al. discloses a sol-gel matrix for capillary electrochromatography, not SPE. As discussed above, because chromatography and SPE are different operations, Tang et al. also do not disclose binding of nucleic acid to a sol-gel matrix.

Further, there is no rationale to pack the fluidic microchip of Christel et al. with the sol-gel matrix of Tang et al. There is no disclosure that the sol-gel matrix of Tang et al. is effective for binding nucleic acid. Tang et al. disclose the sol-gel as a stationary phase for capillary

electrochromatography, not SPE. In fact, one of ordinary skilled in the art would not pack the fluidic microchip of Christel et al. with the sol-gel because doing so would block the silicon oxide surfaces available for DNA binding. Christel et al. go through great lengths to increase the silicon dioxide surface area of their device by constructing 5000 pillars of 200 μm high each (see page 23, right column; and Figs. 2-3). One of ordinary skill in the art would expect that filling the microchip of Christel et al. with the sol-gel of Tang et al. (as suggested by the Examiner) would decrease the silicon dioxide surface area available for binding nucleic acids, because the sol-gel would be in intimate contact with these surfaces. Additionally, because there is no teaching in the prior art that sol-gel can be engineered to bind nucleic acid, one of ordinary skill in the art would conclude that filling the microchip of Christel et al. would significantly decrease the nucleic acid extraction efficiency of that device. As such, there is no expectation of success when one combines the method of Christel et al. with the sol-gel of Tang et al.

The Examiner also relies on Sato et al. to disclose “control of pore size distribution through so-gel process ... and ... pores [*sic*] sizes of ca. 1 micron obtained with certain additives” (Office Action, page 4). However, because Sato et al. fail to cure the deficiencies of Christel et al. and Tang et al., their combination still cannot render the present invention obvious.

Therefore, for the reasons noted above, the combination of Christel et al. with Tang et al. (with or without Sato et al.) does not render the present invention obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

Applicants have responded to the Office Action mailed April 30, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Response or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (119620-00154). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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